

ALOPEXX ONCOLOGY PRESENTS ENCOURAGING RESULTS OF A PHASE I STUDY OF DI-LEU16-IL2 IN RELAPSED/REFRACTORY NHL AT THE AMERICAN SOCIETY OF HEMATOLOGY ANNUAL MEETING

CONCORD, MA, December 5, 2016 -- Alopexx Oncology, LLC announced data from a Phase I trial of DI-Leu16-IL2, a recombinant antibody fusion protein (immunocytokine) composed of interleukin-2 and a CD20-targeting monoclonal antibody. The CD20 antibody recognizes the same target on B cells as Rituxan and maintains the activities of both the antibody and cytokine components but is also involved in tumor targeting, engagement of the immune system, and induction of an anti-cancer vaccine effect.. The results of the study (abstract #95954) were presented at the 58th annual American Society of Hematology (ASH) meeting in San Diego, CA. Alopexx Oncology is a portfolio company of Alopexx Enterprises, LLC.

Twenty-two patients with relapsed or refractory B-cell CD20 positive lymphoma, in 5 dose cohorts, have been enrolled. Fifteen of 18 patients receiving 2 or more cycles of therapy had tumor regression or stabilization including 3 complete and 2 partial responses. The durations of response were over 12 months in many cases. The durability of those responses was maintained in patients months after stopping treatment suggesting a vaccine effect had occurred. These study results are similar to a previous investigator sponsored Phase 1 study conducted at the City of Hope by Dr. Andrew Raubitschek.

Overall DI-Leu16-IL2 was well tolerated as outpatient therapy. Unlike normal IL-2 treatment, the most common toxicities encountered were a mild skin rash that resolved spontaneously. Subcutaneous dosing was employed in the study to deliver the drug directly into the lymphatic system, allowing for higher dosing and lower side effects than with IV infusion. In addition, the effective dose of DI-Leu16-IL2 was 100-200-fold lower than Rituxan. This suggests that by targeting the tumor micro-environment an effective treatment can occur at a much lower dose and opens the door to future combination therapy with established drugs like immune checkpoint inhibitors.

“The findings to date are very encouraging and support our belief that DI-Leu16-IL2 has the potential to become a effective therapy in the treatment of refractory NHL either alone or in combination.” said Dr. Daniel Vlock, founder and CEO of Alopexx Enterprises.

About DI-Leu16-IL2

CD20 is a protein frequently expressed on cancer cells associated with NHL. Pre-clinical studies have shown that DI-Leu16-IL2, which has activities of both the anti-CD20 antibody and cytokine components, targets the tumor cells, engages the immune system and has the potential to produce an anti-cancer vaccine effect. As a result of this vaccine-like effect, long-term anti-cancer activity should continue and future cancer cells could be destroyed even without the need for re-dosing.

“The fusion of the anti-CD20 antibody and the cytokine IL2 creates an effect that is far more powerful than administering those therapeutics individually or in combination,” explained Stephen Gillies, Ph.D., Chief Scientific Officer of Alopexx Oncology. “In this therapeutic approach the drug elicits a T-cell response and also activates the innate immunity to kill tumor cells, and that is a very important distinction between this and other treatments.”

About Alopexx Oncology/Alopexx Enterprises

Alopexx Oncology, LLC, a portfolio company of Alopexx Enterprises, licensed the rights to develop and commercialize its lead drug candidate DI-Leu16-IL2 from Provenance Biopharmaceuticals Corp. in 2011. Alopexx Enterprises consists of experts with deep industry knowledge and technical expertise in all areas of drug development including, pharmacology, CMC, toxicology, medical and clinical operations, quality and regulatory affairs. Alopexx forms collaborations with academic institutions, biotech and pharmaceutical companies to advance its portfolio to deliver breakthrough therapies to patients in need. For more information, please visit www.alopexx.com.

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